

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

58FR27495
5-10-93

21 CFR Part 1040

[Docket No. 93 N-0044]

Laser Products; Intent to Amend Performance Standard

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

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SUMMARY: The Food and Drug Administration (FDA) is considering amendments to the Federal performance standard for laser products to achieve greater consistency between the requirements applicable under that standard and the International Electrotechnical Commission (IEC) standards for laser products and medical laser products. Additional proposed changes to the Federal standard that are unrelated to harmonization are being considered as a result of FDA experience in enforcing the present laser standard and processing variances. The changes would, in many cases, reduce the regulatory burden on affected manufacturers (without compromising public health) and generally would improve the effectiveness of FDA's regulation of laser products.

DATES: Written comments and data by (*insert date 90 days after date of publication in the Federal Register*).

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patricia Dubill, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 31, 1975 (40 FR 32252), FDA published the performance standard for laser products in part 1040 (21 CFR part 1040) as a final rule. The standard became effective on August 2, 1976. In the Federal Register of November 28, 1978 (43 FR 55387), and again on August 20, 1985 (50 FR 33682), FDA amended the standards. The experience of FDA in the administration of the laser standard since the last amendments indicates that some provisions of the standard may need to be amended. Identification of the need for many of the changes under consideration stemmed largely from extensive FDA involvement in international standardization efforts for laser products with IEC, an international standards development organization with participants from many countries. FDA has made a considerable contribution to the development of the IEC laser standards and believes that greater consistency between the FDA standard and the IEC standards will result in an improved FDA standard, improved compliance, and a more efficient enforcement program. Other changes to the FDA laser standard that are unrelated to harmonization with the IEC standard were determined to be needed as a result of FDA's continuing effort to evaluate new information and experience enforcing the present laser standard and processing variance applications.

For requirements under §1040.10 (21 CFR 1040. 10), the proposed changes would: (1) Increase the accessible emission limits (AEL) set forth in Tables I through III–B of §1040. 10(d) in the red and near infrared portions of the spectrum; (2) establish a maximum classification time for Class I laser products that emit visible or infrared radiation that is not intended to be viewed; (3) establish the AEL for Class IIIa laser products having invisible emission; (4) reduce the AEL of Class I for repetitively pulsed lasers; (5) expand the infrared wavelength range for which military “eye safe” data are available; (6) modify the measurement parameters for classification; (7) increase the levels of laser radiation for which safety interlocks are required; (8) delete the requirements for beam attenuators and emission indicators for Class II and Class IIIa laser systems;

(9) establish a requirement for emission indicators for remote laser apertures; (10) eliminate an aspect of the scan fail safeguard requirement; (11) allow acceptance of the IEC warning and explanatory labels as alternates to the presently required warning logotypes; (12) alter the required wording for protective housing labels; and (13) eliminate some requirements for information in the user instructions.

For requirements under §1040.11 (21 CFR 1040.11) for specific purpose laser products, FDA is considering several additional requirements, including requiring an additional warning for promotional material for Class II and Class IIIa demonstration products and requiring a laser emitting warning, emergency stop control, and laser operation monitor for Class IIIb and Class IV medical laser products. The latter requirements are being considered in order to achieve consistency with the newly approved IEC 60 1-2-22 standard for medical lasers.

It should be noted that this notice of intent to amend the laser standard should not be construed as a commitment to the changes discussed being formally proposed or adopted. This document is for the purposes of serving notice that amendments to the standard are being considered and inviting comments and recommendations from all concerned. Although some of the changes under consideration would, if adopted, reduce the level of controls, indicators, and warnings for some laser products, FDA will pursue such changes only if it is confident that no additional risk of injury will result from the changes. This is in keeping with FDA's primary responsibility of protecting the public health.

This notice is being issued under FDA's policy of seeking early public participation in radiation safety standard amendment activities. Details concerning the rationales for the amendments under consideration are discussed below.

II. Amendments Under Consideration

1. FDA is considering amending § 1040.10(d) to increase the AEL in the spectral range from 500 to 1,400 nanometers (nm) for emission durations of 10 seconds or longer. FDA believes that there are accepted biological data and publications in peer-reviewed journals that support this

increase and notes that similar adjustments have already been adopted in the IEC 825 and American National Standards Institute (ANSI) Z-136.1-1986 standards. Because the structure of the tables of the AEL in the FDA standard have been in place for many years, and because manufacturers of products intended for United States market are familiar with their use, modification of the AEL might be accomplished by redefining the factor k_1 for this spectral range in § 1040.10(d), Table IV.

2. FDA is considering amending § 1040.10(d) to reduce the emission durations to be used for the classification of Class I laser products that emit visible or infrared laser radiation not intended for human exposure or to be viewed, as determined from the design of the product or its intended function. For such products, the maximum emission duration to be considered for the purpose of classification would be 100 seconds. The rationale for this proposal is that an unnecessary burden is imposed by the present requirement to consider emission durations of greater than 104 seconds in all cases. Visual fixation for such durations requires immobilization of the body, and such prolonged exposure of the cornea or skin to emissions from many kinds of laser products is unreasonable. A **maximum** emission duration of 100 seconds is considered more reasonable given these considerations. However, for products for which viewing or exposure is intended or inherent in the design of the product, the classification time would remain unchanged at greater than 104 seconds.

FDA is suggesting that the classification determination be made on the basis of whether a laser product is intended for a specific or for a general purpose. General-purpose laser products such as laboratory laser systems or surveying lasers would be classified for emission durations of greater than 104 seconds, whereas laser products such as point-of-sale scanners, machine vision products, or fiber optic communication products would be classified using the shorter classification time. The reduced classification time would also be utilized in evaluating the levels of interior laser radiation fields for the purpose of determining the applicability of requirements for safety interlocks and protective housing labels. ..

3. There are at present no AEL in the ultraviolet and infrared wavelength ranges for Class IIIa. FDA is considering an amendment to § 1040.10(d), Table III–A, to establish such limits. FDA believes that the present transition at invisible wavelengths from Class I to Class IIIb is too abrupt. At the AEL of Class I, no hazard is recognized to exist, and there are no requirements for safety performance features or warning labels. Those products that exceed the AEL of Class I by any amount at invisible wavelengths are Class IIIb products and are required to incorporate almost all performance features and severe warnings on the labels. By having a transition in Class IIIa, there would be a more graded approach to addressing the minimal hazard of those products whose accessible levels slightly exceed the AEL of Class I. Hence, FDA is considering Class IIIa AEL for those invisible wavelengths that do not exceed the AEL of Class I by greater than a factor of five. This approach is already incorporated into both the IEC and ANSI standards.

4. FDA is also considering proposing amendments to § 1040.10(d) to reduce the AEL of Class I for repetitively pulsed lasers. Accepted biological research indicates that the hazard from repetitive pulses is not simply additive, i.e., effects occur which make such lasers more hazardous than simple addition of the pulse energies would indicate. Thus, FDA is considering proposing to introduce a factor of $N^{1/4}$, where N is the number of pulses in the emission duration under consideration. This correction of the AEL is already incorporated into the IEC and ANSI standards.

5. FDA is considering expansion of the wavelength range for “eye safe” infrared laser radiation. The current range is from 1,535 nm to 1,545 nm. FDA believes that there is a need to amend Tables IV and V of § 1040.10(d) in deference to current biological knowledge.

6. FDA is considering amendment of Tables I through VI of § 1040. 10(d), the AEL of the classes of laser products, to respond to recent data in optical radiation biological effects research and to more closely conform the tables to the class limits in the IEC and ANSI standards. However, it is the intention of FDA to preserve the present structure of the tables if at all possible because U.S. manufacturers of laser products are accustomed to working with these tables. The tables are simpler to use than those in the IEC and ANSI standards in that they have fewer correction factors.

FDA will attempt to combine as many biological dependencies as possible into as few correction factors as possible.

7. The current parameters for the measurement of radiant power or energy established in § 1040.10(e)(3) require the use of a 7 millimeter (mm) diameter circular aperture for products unlikely to be viewed with optical instruments and the use of collimating optics of 5 diopters or less (which implies a measurement distance of 20 centimeters (cm)). FDA believes that the 20 cm measurement distance is not sensitive to the ability of young and myopic persons to accommodate objects at closer distances. A distance of 10 cm could be acceptable to such persons. Additionally, a 7 mm aperture is generally overly conservative, and there is literature confirming that the pupil of the eye constricts when an object at a very close distance is viewed. Revisions to these measurement requirements are therefore under consideration, and FDA believes that the IEC committee will consider like requirements. The final determination regarding whether FDA will propose a revision of this section will depend partly on the outcome of recently proposed amendments to the ANSI and IEC standards.

8. FDA is considering an amendment to relax the laser radiation levels for which the requirements of § 1040.10(f)(2) are applicable. This relaxation will require safety interlocks only to prevent access to laser radiation levels in excess of Class IIIa unless: (1) The radiation is emitted directly through the opening caused by opening of the protective housing; or (2) the Class IIIa levels are contained within the protective housing of a Class I, IIa, II, or IIIa laser product. Since the IEC standard only requires safety interlocks to prevent access to Class IIIb or IV levels that exceed the class of the product (embedded lasers), safety interlocks are never required by that standard for Class IV products. This amendment would be intended to close the gap between the two standards and may result in the IEC adopting a similar requirement.

9. FDA is considering relaxing the requirements of § 1040.10(f)(5) and (f)(6) by eliminating requirements for emission indicators and beam attenuators for Class I and IIIa laser systems. These amendments would achieve consistency with both the IEC and the ANSI standards for emission

indicators and with the IEC standard for beam attenuators. As a further consideration, under authority granted by §1040.10(f), FDA has issued numerous approvals of alternate means of safety, such as emission controls, to provide the safety afforded by a beam attenuator. FDA believes that it is clear that, in the lower classes, the safety of the laser system is not improved by the presence of a beam attenuator when there is an immediate control for the termination of emission.

10. FDA is considering amendment of §1040.10(f)(5) to require visible indications of actual emission from remote laser apertures of Class IIIb and Class IV laser systems. This requirement would be in addition to the present requirements, as applicable. The agency has become aware of industrial material processing machines that use a single high-power laser system shared in time between more than one work station or aperture. The agency believes that it is important that persons in the vicinity of remote apertures be alerted when there is emission so that appropriate measures can be taken to avoid exposure.

11. FDA is considering deletion of §1040.10, which requires a scan failure safeguard to prevent human access to laser radiation exceeding the AEL of the class of the scanned laser radiation. This requirement applies if the laser product is Class IIIb or IV, and the AEL of Class IIIa would be exceeded solely as a result of a failure causing a change in either scan velocity or amplitude. Deletion of the requirement is under consideration because there has been considerable difficulty in understanding the requirement since its implementation in 1986. There are no plans to propose changing the requirement in §1040.10(f)(9)(i) for a scan failure safeguard to prevent human access to laser radiation that exceeds the AEL of the product class as a result of any failure causing a change in either scan velocity or amplitude.

12. FDA is considering amending the warning logotype label requirements to allow the IEC warning and explanatory labels as alternatives to the presently required labels. This would permit a uniform system of labeling and class designations under both standards. The current requirements of §1040.10(g)(1) through (g)(4) require the use of logotypes described in the American National

Standard for Product Safety Signs and Labels, ANSI Z-535.4-1 991. The ANSI logotypes require the signal word “CAUTION” for Class H and Class IIIa products with an irradiance less than or equal to 2.5×10^{-3} watts per square centimeter (W/cm^2), and the signal word, “DANGER,” for Class IIIa products with an irradiance greater than $2.5 \times 10^{-3} \text{ W}/\text{cm}^2$ and for all Class IIIb and Class IV products. These paragraphs also require the use of Roman numerals for the laser class designation on the warning logotypes. The IEC labels allow the use of Arabic numerals for the class designations and do not require use of the signal words. FDA believes that such an amendment will make compliance with this requirement easier for manufacturers that sell to both U.S. and international markets. Further, since the ANSI laser standard permits the IEC labels, and because there is confusion as to the classification of medical laser products in the United States (because Roman numerals are used to designate both the laser product hazard class and the medical device class), FDA believes that such an amendment, which will reduce the confusion, would be desirable. However, it is important that the FDA and IEC standards be in agreement on the designations and AEL of the classes for this change to be meaningful.

13. FDA is also considering an amendment to § 1040.10 (g)(6) to permit the word, “CAUTION,” in place of the word, “DANGER,” to achieve uniformity with the IEC standard. Acceptance of alternate schemes such as symbols to provide these warnings may also be considered.

14. FDA is considering simplifying and making more uniform the requirements of § 1040.10(g)(6) and (g)(7) for labels for **noninterlocked** and defeatable interlocked protective housings. The present label wordings depend on the level of the internal laser radiation with the protective housing open or removed and are a complex matrix.

15. FDA is considering simplifying § 1040.10(h)(1) and adding a requirement for the hazardous area surrounding a laser product to be identified in the user instructions. FDA will also consider making other requirements of this section less specific to permit greater flexibility in providing the required instructions for user safety.

16. FDA is considering amendment of § 1040.11(a) for medical laser products to require a visible or audible indication during actual emission of laser radiation in excess of the AEL of Class IIIa from a medical laser product. This requirement is being considered in order to bring the FDA standard into closer agreement with the requirements of IEC standard 601-2-2 for medical laser equipment. The emission indicator presently required by § 1040.10(f)(5) on Class IIIb and Class IV medical laser products provides its indication sufficiently prior to laser emission for people in the vicinity to take action to avoid exposure. On existing laser devices, the delay in actual emission from the time of the indication has been observed to range from a few seconds to some minutes. However, this indicator may continue to provide its indication for an extended time while the product is in a standby mode and not actually emitting, decreasing its value as an alarm. The proposed amendments would incorporate the approach used in the IEC standard, which reflects the concern that people in the vicinity should be alerted while the laser is actually emitting and when precautions are actually required to avoid exposure.

17. FDA is considering amendment of § 1040.11(a) to require an emergency laser stop control for Class IIIb and Class IV medical laser products. This requirement would bring the FDA standard into closer agreement with the requirements of IEC standard 601-2-22. The emergency stop control could be a panel or foot switch readily accessible to the operator of the product. This control would provide an alternate and additional control to the key-actuated master control required under § 1040.10(f)(4), or any other such control that might be present for the purpose of terminating laser emission in response to emergencies or unintended occurrences.

18. FDA is considering amendment of § 1040.11(a) to require optical or electrical monitoring of the operation of lasers in Class IIIb and Class IV medical laser products. This requirement is being considered in order to bring the FDA standard into closer agreement with the requirements of IEC standard 601-2-22. The monitoring of the operation of the laser is intended to warn the operator of excessive fluctuations in laser emission or excursions from a set level of emission. This requirement would be in addition to the present requirement of § 1040.11(a)(1) that the laser

product incorporate a system for measurement of the level of laser radiation intended for irradiation of the human body. In many cases the meeting of the present requirement may satisfy the proposed requirement; however, an additional means of monitoring would be required for those laser products in which the output is only measured occasionally, such as before a procedure or between patient exposures.

19. FDA is considering amendment of § 1040.11(c) to require specific warnings in the user instructions for demonstration laser products against exposure of spectators to laser radiation in excess of Class I AEL. When this section was amended to allow the promotion of Class IIIa demonstration laser products, the proliferation in these products that occurred was not anticipated. In the preamble to the amendment, FDA expressed its policy that the same restrictions applicable under variances to Class IIIb and Class IV laser products, against exposure of the public to hazardous levels of laser radiation should also apply to the lower classes for which variances are not required. However, since the amendments were published, FDA has become aware of some instances of promotion of Class IIIa demonstration laser products for direct exposure of the public by trade show exhibitors and promotional pictures depicting such practices. For this reason, FDA believes it is appropriate to require manufacturers to publish warnings that these products are not to be used for exposure of the public to ensure that this information is available to purchasers and users.

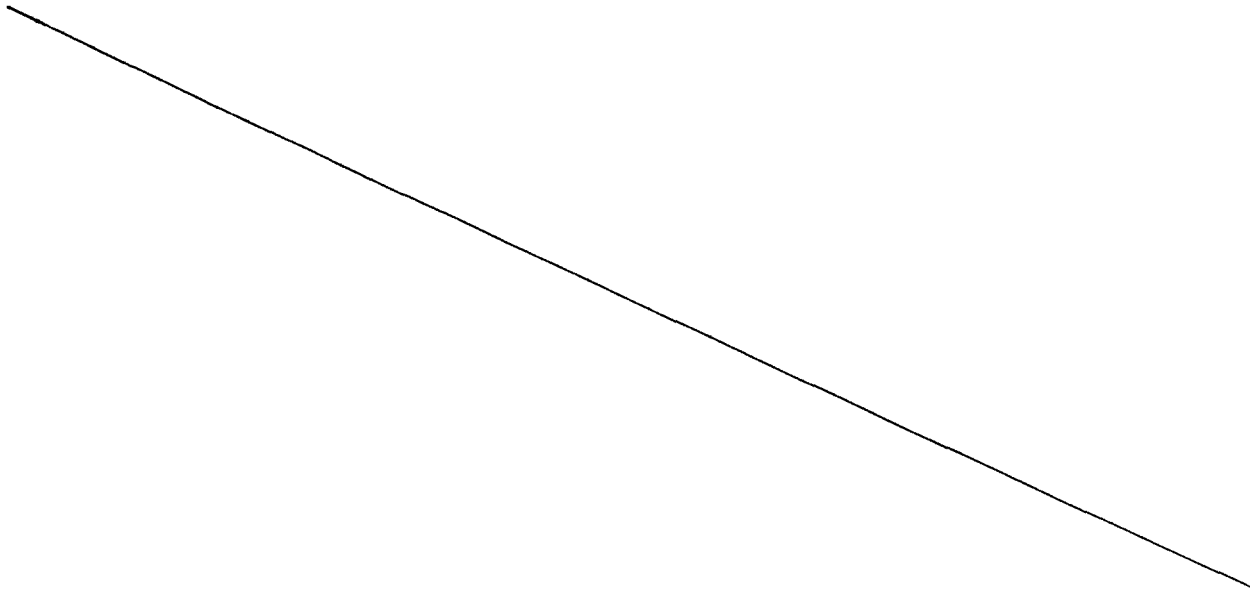
III. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FDA is preparing to present its proposals to amend the standard to the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) prior to the publication of proposed amendments in the Federal Register. TEPRSSC is an advisory committee established by the Radiation Control for Health and Safety Act of 1968 to provide consultation before the Commissioner of Food and Drugs prescribes any performance standard for an electronic product. An opportunity for public comment will be provided in conjunction with the presentation to TEPRSSC, in addition to the opportunity being provided with this notice. All comments received will be considered to the fullest possible extent in formulating the proposed amendments.

IV. References

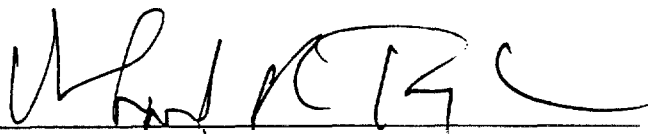
The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. IEC 825: "Radiation Safety of Laser Products, Equipment Classification, Requirements and User's Guide," American National Standards Institute, 11 West 42d St., New York, NY 10036, 1984.
 2. IEC 825: Amendment to IEC 825 (1984), available as above, 1990.
 3. IEC 60 1-2-22: "Medical Electrical Equipment, Part 11: Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment, " available as above, 1992.
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4. Z-1 36,1: "American National Standard for the Safe Use of Lasers," Laser Institute of America, 12424 Research Pkwy., suite 130, Orlando, FL 32826, 19%5.

5. Z-535.4: "American National Standard for Product Safety Signs and Labels," National Electrical Manufacturers Association, 2101 L St. NW., Washington, DC 20037, 1991.

Dated: 4/23/93
April 23, 1993

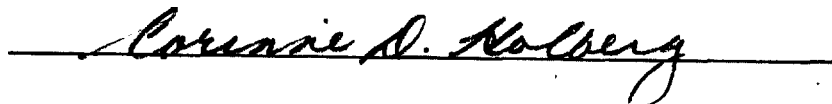


Michael R. Taylor
Deputy Commissioner for Policy

[FR Dec. 93-'??'?? Filed '??-'??-93; 8:45 am]

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REFERENCES: DOCKET #93N-0044

Laser Products; Intent to Amend Performance Standard

1. IEC 825: "Radiation Safety of Laser Products, Equipment Classification, Requirements and User's Guide," Available from the American National Standards Institute, 11 West 42nd Street, New York, NY 10036, 1984.
2. IEC 825: Amendment to Publication 825(1984). Available as above, 1990.
3. IEC 601-2-22: "Medical Electrical Equipment, Part II: Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment. " Available as above, 1991.
4. **Z-136.1:** "American National Standard for the Safe Use of Lasers. " Available from the Laser Institute of America, 12424 Research Parkway, Suite 130, Orlando, FL 32826, 1986.
5. Z535.4: "American National Standard for Product Safety Signs and Labels. " Available from the National Electrical Manufacturers Association, 2101 L Street, N. W., Washington, DC 20037, 1991.

[Note: There are no pages missing from the first 3 references, although it may appear that way. Every other page of those documents is in French, so the French pages were removed. All of the English pages are present.]

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XEROX MANAGEMENT BRANCH